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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,696	06/06/2006	Nicola Dioguardi	09728.0347USWO	2949

23552   7590   09/04/2008
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EXAMINER
FITZPATRICK, ATIBA O

ART UNIT	PAPER NUMBER
2624	

MAIL DATE	DELIVERY MODE
09/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
	10/563,696	DIOGUARDI ET AL.
Office Action Summary	Examiner	Art Unit	
	ATIBA O. FITZPATRICK	2624	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS,
WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>06 June 2006</u>.

2a) ☐ This action is **FINAL.**   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>1-29</u> is/are pending in the application.

     4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>1-29</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

     a) ☐ All b) ☐ Some * c) ☐ None of:

         1. ☐ Certified copies of the priority documents have been received.

         2. ☐ Certified copies of the priority documents have been received in Application No. _____.

         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

     * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/05/2006</u>.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Specification

The title of the invention is not descriptive. A new title is required that is clearly

indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because the abstract length exceeds 150

words. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 4 and 5 are objected to because of the following informalities: These claims

include the words "a" and "microscopy" or "ophtalmoscopy" in the same phrase, but this

is grammatically incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or
any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and
requirements of this title.

Claims 27-29 are rejected under 35 U.S.C. 101 because the claimed invention is

directed to non-statutory subject matter. Claim 27 includes a description of a system

with distinct structure-type limitations included therein, but claim 27 depends from claim

1, which pertains to a method. Therefore, it is not clear, which singular statutory

category claim 27 should fall into. Claim 28 includes the limitation "software program",

which does not fall into any statutory category. Claim 29 includes the limitation "computer readable support comprising", but the phrase "support comprising" does not necessitate that the program is stored on a medium. It is required that the claim explicitly state that the program is stored on the medium. Also, the term "support" is not necessarily a medium. This term is not used anywhere in the specification in order to provide an understanding of the scope of this term. Note that a signal does not fall into any statutory category.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1, 16, and 20 use the phrase "and/or" (at least once in each claim). Note that for this phrase to be enabled, the alternatives must be included in at least 3 separate embodiments in the specification. Several separate embodiments must exist wherein only one of the alternatives is being used in each embodiment respectively, and one embodiment must exist wherein all alternatives are being used together.

Claim 29 uses the term "support", which is not referenced anywhere in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 5 recite the limitation "the original delta-intensity". There is insufficient antecedent basis for this limitation in the claim. Claim 13 recites the limitations "the direction's line" and "the two next pixels in the direction". There is insufficient antecedent basis for these limitations in the claim. Claim 24 recites the limitation "the distance". There is insufficient antecedent basis for this limitation in the claim. Claim 25 recites the limitations "the overall volume", "the sum of", and "the single volumes". There is insufficient antecedent basis for these limitations in the claim.

Regarding claim 13, the phrase "such" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 24, the phrase "multiplying the area calculated according to step 1i) for the distance between the first section's image and the subsequent section's image" is unclear and does not make sense. This phrase does not state what to multiply

the area by. Also, the office does not understand what is meant by "multiplying the area

... for the distance...". Does this means that the area pertains to the distance?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form

the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 11, 20, 24, 28, and 29 are rejected under 35 U.S.C. 102(b) as being

anticipated by USPN 5016173 (Kenet).

As per claim 1, Kenet teaches a method of processing digital images comprising one or

more objects to be quantified **(Note that only one object is required)**, the method

comprising the following main stages **(Limitations present only within the preamble**

are not given patentable weight):

normalization of the digital images **(Kenet: Fig. 3: 314 and 316; col 10, line 66—col**

11, line21: "pixel scaling factors to apply to all pixels of an image that will result

in standardization of color between images": Note that to normalize means to

make normal or cause to conform to a norm or standard; Col 11, line 40 – col 12,

line 30: the transformation steps comprise normalization (see equations));

quantization of the images to one bit **(Kenet: Fig. 3: 312 and 320; col 4, lines 52-67:**

quatization with pixel depth up to 32 bits; col 10, lines 20-30; col 15, line15 – col

16, line 67: "resulting a binary image": segmentation), further comprising at least one of the following stages **(Note that only one of the following stages is required)**:

- calculating, from the images quantized to one bit, the perimeter, area **(Kenet: Fig. 3: 322; col 20, lines 29-35: "diameter and area")** and/or **(Note that only one of these alternatives is required)** fractal dimension of the one or more objects to be quantified **(Kenet: Fig. 3: 322; col 19, line 56 – col 20, line 29)**;

- reconstructing, from the images quantized to one bit, a 3D-image of the one or more objects to be quantified **(Kenet: Fig. 3: 218; col 13, line 14 - col 14 – line 67: "3D surface recontruction"; col 16, lines 20-50: "count the number of blobs representing lesions (foreground)"; col 18, lines 22-29; col 18, lines 51-56: "quantified": quantification)**, and/or

- calculating, from the normalized images, the fractal dimension of the overall image **(Note that only one of the preceding stages is required. Kenet: Fig. 3: 322; col 19, line 56 – col 20, line 29)**.

As per claims 10 and 11, arguments made in rejecting claim 1 are analogous to arguments for rejecting claims 10 and 11.

As per claim 20, Kenet teaches a method according to claim 1, further comprising a stage of 3D-reconstruction (3D-R) performed on the image subjected to the IMA-EL stage, the 3D-R stage comprising the following steps **(Limitations present only within the preamble are not given patentable weight)**:

1g) overlapping each image with the subsequent image along the z axis; 2g) minimizing the difference of brightness and/or colour intensity between overlapping pixels by shifting along the x axis and/or the y axis an image with respect to each other; 3g) repeating steps ig) and 2g) for each pair of adjacent images **(Kenet: col 13, line 14 – col 14, line 67: "(4) For each stereo pair of thresholded gradient images determine the location of corresponding epipolar lines in the left and right images. Place a window of predetermined size on the first feature point of the first epipolar line in the left image of a stereo image pair.**

(5) Then search along the corresponding epipolar line in the right image using a sequential similarity different algorithm (SSDA) to minimize a distance measure, D.sub.w, between one or more stereo pairs of left and right thresholded gradient images, within a window, w, of size, n by m pixels, as follows: ##EQU1## where F.sub.L is the left image, F.sub.R is the right image, V.sub.w is the variance within the window w, and i and j are the horizontal and vertical pixel position indices within the window.").

As per claim 24, Kenet teaches a method according to claim 1, further comprising a stage of volume calculation (V-CLC) which comprises the following steps **(Limitations present only within the preamble are not given patentable weight)**:

li) calculating the area of each object in a first 2D-image corresponding to a first object's section; 2i) multiplying the area calculated according to step li) for the distance between the first section's image and the subsequent section's image, taken in the z direction of

scanning, wherein an image of the same object is contained; 3i) reiterating steps Ii) and
2i) for each section's image in the order **(Kenet: col 18, line 66 - col 19, line56: "The
convex deficiency of the border is then obtained by subtracting the area of the
lesion (i.e. the number of pixels or square millimeters obtained within the border)
from the area within the convex hull. This is then normalized by dividing it by the
area of the lesion and then multiplying it by 100. The convex deficiency of the
border thus quantifies the area of any concave indentations into the lesion as a
percentage of the lesion's area"; col 20, lines 30-35: "The area is computed by
counting the number of pixels within the border and then multiplying by the scale
factor determined in the spatial calibration sequence above"; Note that this
process is repeated for each lesion area).**

As per claim 28, Kenet teaches a software program (PRG) to perform the method
according to claim 1 **(Kenet: Figs. 1 and 3; col 8, lines 13-18; col 3, line 66 – col 4,
line 5).**

As per claim 29, Kenet teaches a computer readable support comprising a program
(PRG) to perform the method according to claim 1 **(Kenet: Figs. 1 and 3; col 8, lines
13-18; col 3, line 66 – col 4, line 5).**

35 USC 103 – Claim Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
such that the subject matter as a whole would have been obvious at the time the invention was made to a
person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived
by the manner in which the invention was made.

Claims 4, 5, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over

USPN 5016173 (Kenet) as applied to claim 1 above, and further in view of "Estimation

of three-dimensional connectivity of internal defects in coatings using fractal analysis"

JOURNAL OF THERMAL SPRAY TECHNOLOGY, vol. 10, no. 2, June 2001, pps. 287-

292 (Llorca-Isem).

As per claim 4, Kenet teaches a method according to claim 1, wherein the digital image

has been acquired by a microscopy **(Kennet: col 5, lines 11-27)**. Kenet does not teach

confocal microscopy.

Llorca-Iscern teaches confocal microscopy **(Llorca-Iscern: abstract: "confocal**

scanning laser microscope").

Thus, it would have been obvious for one of ordinary skill in the art at the time the

invention was made to implement the teachings of Llorca-Iscern into Kenet since Kenet

suggests a fractal analysis system using a microscope in general and Llorca-Iscern

suggests the beneficial use of a fractal analysis system using a confocal scanning laser

microscope since it is a "useful tool with minimum interactions between the sample and

the technique" (Llorca-Iscern: introduction: page 287, para 2) in the analogous art of

image processing.

As per claim 5, arguments made in rejecting claim 4 are analogous to arguments for

rejecting claim 5.

As per claim 27, Kenet teaches a system (i) for acquiring and processing an image

including a microscope (2), electronic image acquisition means (6) operatively

connected to said microscope (2), a processing system (7) operatively connected with

said microscope (2) and said image acquisition means (6), said processing system (7)

comprising a processing unit 25 (CPU), storing means which include a RAM working

memory and a hard disk, said processing system (7) running a program (PRG) to

perform a method according to claim 1 **(Kenet: Figs. 1-3; co; 4, line 7 – col 10, line

37)**. Kenet does not teach a confocal scanning microscope.

Llorca-Iscern teaches confocal microscopy **(Llorca-Iscern: abstract: "confocal

scanning laser microscope")**.

Claims 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN

5016173 (Kenet) as applied to claim 1 above, and further in view of Spiliotis, I.M. et al.

"Fast algorithms for basic processing and analysis operations on block-represented

binary images" PATTERN RECOGNITION LETTERS, NORTH-HOLLAND PUBL., vol.

17, no. 14, Dec. 30, 1996, pps. 1437-1450 (Spiliotis).

As per claim 12, Kenet teaches a method according to claim 1, further comprising a

stage of image quantification which comprising at least one of the following steps

(Limitations present only within the preamble are not given patentable weight:

calculating the area A of the object under examination by counting the number of pixels

belonging to the cluster of active pixels selected according to the previous IMA-EL stage

(Kenet: col 19, lines 40-50: "area of the lesion (i.e. the number of pixels or square

millimeters obtained within the border)"; col 20, lines 30-35: "The area is

computed by counting the number of pixels within the border and then

multiplying by the scale factor determined in the spatial calibration sequence

above"). Also, note that Kenet does determine the edge pixels of the objects **(Kenet:**

col 16, lines 50-55).

Kenet does not teach calculating the area A of the object under examination by counting

the number of pixels belonging to the cluster of active pixels;

calculating the perimeter P of the object under examination by i) selecting the object

contour's pixels, and ii) applying to such selected pixels a perimeter calculation's

algorithm, wherein to each active pixel belonging to the object is given a "perimeter

value", which is a function of the position of the active pixels adjacent to the pixel under

examination, the sum of said "perimeter values" being the overall perimeter P of the object.

Spiliotis teaches calculating the area A of the object under examination by counting the number of pixels belonging to the cluster of active pixels **(Spiliotis: page 45: section: 5.3. Area measurement)**;

calculating the perimeter P of the object under examination by i) selecting the object contour's pixels, and ii) applying to such selected pixels a perimeter calculation's algorithm, wherein to each active pixel belonging to the object is given a "perimeter value", which is a function of the position of the active pixels adjacent to the pixel under examination, the sum of said "perimeter values" being the overall perimeter P of the object **(Spiliotis: pages 1427 and 1428: section: introduction: "the boundary-based representations include chain encode,… contour control point models…"; pages 1444-1445: sections: 5.1 and 5.2: "The measurement of the perimeter is simply the count of the edge pixels")**.

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to implement the teachings of Spiliotis into Kenet since Kenet suggests a system that calculates certain features of binary regions including area and edge in general and Spiliotis suggests the beneficial use of a system that calculates certain features of binary regions including area and edge wherein the area is determined by summing pixels in a region and the determined region-edge is used for

determining the perimeter. These particular methods are used in Spiliotis as for "low time complexity and are suitable for very fast processing rates… the time complexity is significantly lower in comparison to the implementations that are based on the 2-D array" (Spiliotis: page: 1438, section: introduction) in the analogous art of image processing.

Claims 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5016173 (Kenet) as applied to claim 24 above, and further in view of USPN 6102291 (Mazzone).

As per claim 25, Kenet teaches a method according to claim 24. Kenet does not teach wherein the overall volume of the objects in the examined tissue is determined as the sum of the single volumes.

Mazzone teaches the overall volume of the objects in the examined tissue is determined as the sum of the single volumes **(Mazzone: col 9, lines 5-13: "it is finally possible to calculate the overall area of detection surface 3a of the object 3 as the sum of the single elementary areas calculated": Note that area is volume when considering 2D)**.

Thus, it would have been obvious for one of ordinary skill in the art at the time the

invention was made to implement the teachings of Mazzone into Kenet since Kenet

suggests a system using a laser scanner for imaging, image processing for detecting

objects in the created image, and determining the area of the individual objects in

general and Mazzone suggests the beneficial use of a system using a laser scanner for

imaging, image processing for detecting objects in the created image, and determining

the area of the individual objects wherein the overall area of all objects is determined by

summing the individual in the analogous art of image processing. It would have been

obvious for one of ordinary skill in the art at the time the invention was made to

implement the summation of individual areas to determine the overall area since this

method would be most accurate. Furthermore, one of ordinary skill in the art at the time

the invention was made could have combined the elements as claimed by known

methods and, in combination, each component functions the same as it does

separately. One of ordinary skill in the art at the time the invention was made would

have recognized that the results of the combination would be predictable.

Claims 2, 3, 6-9, 13-19, 21-23, and 26 would be allowable if overcome the rejections

under 35 U.S.C 112,1st and 2nd paragraphs and rewritten in independent form including

all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Atiba Fitzpatrick whose telephone number is (571) 270-

5255. The examiner can normally be reached on M-F 10:00am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Samir Ahmed can be reached on (571)272-7413. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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